



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,614	01/09/2002	Ya Fang Liu	YFLU-P03-001	6176

64175 7590 01/17/2008  
CEPHALON, INC.  
c/o MCCARTER & ENGLISH, LLP  
Renaissance Centre  
405 N. King Street, 8th Floor  
WILMINGTON, DE 19801

EXAMINER
----------

HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
----------	--------------

1651

MAIL DATE	DELIVERY MODE
-----------	---------------

01/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/042,614

Applicant(s)

LIU, YA FANG

Examiner

Susan Hanley

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33,34 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33,34 and 44-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The response and amendment filed 8/9/07 are acknowledged.

Claims 33, 34 and 44-47 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Response to Arguments*

Applicant's arguments with respect to claims 33, 34 and 44-47 have been considered but are moot in view of the new ground(s) of rejection. The rejections under 35 USC 103 are conditionally withdrawn, see below.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 34 and 44-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 33 has been amended to include additional steps for assessing a compound's ability to specifically inhibit JNK. The first step, parts (a) and (b), are drawn to an in vitro phosphorylation assay with neuronal cells with and without the test compound. The second step, (c), comprises an added assay wherein the ability of the candidate compound to inhibit JNK is assessed

by measuring apoptosis in transfected neuronal cells with and without the test compound. The third step (d), comprises comparing the results of the first and second steps. The fourth step, (e)-(h), is drawn to the administration of the test compound to a mammal, harvesting the neuronal tissue and determining apoptosis in the tissue. The last step (h) is now drawn to a correlation of the apoptosis inhibition results obtained from the transfected cells (d) and the tissue biopsy (h). This last step is deemed to constitute NEW MATTER because the specification as-filed does not support the now-claimed a correlation step between the inhibition of apoptosis in transfected neuronal cells and tissue obtained from a test animal.

In the "Summary of the Invention" section, the specification discloses on page 5, lines 15-26 that potential JNK inhibitors can be tested on an animal having a neurological condition. The next lines teach incubating a neuronal cell line in the presence of an JNK inhibitor, contacting the surviving cells with an agent that induces apoptosis and a comparison of the results of the first two steps. There is no disclosure of correlating the apoptosis results with a tissue section of an animal. Likewise, the "Detailed Description of the Invention" section lacks support for the indicated correlation step. The bridging paragraph on pages 17-18 provides detail on testing a compound on an animal and determining apoptosis from a tissue sample. However, this type of assay is not discussed in conjunction with any other disclosed JNK assay. It is clearly a stand-alone test. Therefore, the inclusion of a correlation step of the JNK inhibition between transfected cells and a mammalian tissue sample is NEW MATTER. Because the claims encompass a correlation step between results that is neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

*Claim Rejections - 35 USC § 103*

The rejection of claims 33, 34, 44 and 47 under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 6,943,000; "Davis") in view of Reynolds et al. (1997; "Reynolds") is held in abeyance pending Applicant's response to the New Matter rejection.

The rejection of claims 33, 34, 44, 46 and 47 under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 6,943,000; "Davis") in view of Reynolds et al. (1997; "Reynolds"), as applied to claims 33, 34, 44 and 47, in further view of Liu (1997; cited in the Office Action mailed on 6/14/05) is held in abeyance pending Applicant's response to the New Matter rejection.

The rejection of claims 33, 34, 44, 45 and 47 under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 6,943,000; "Davis") in view of Reynolds et al. (1997; "Reynolds"), as applied to claims 33, 34, 44 and 47, in further view of Gnegy et al. (1976, "Gnegy") is held in abeyance pending Applicant's response to the New Matter rejection.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the

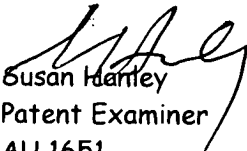
Art Unit: 1651

date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Susan Hanley  
Patent Examiner  
AU 1651



SANDRA E. SAUCIER  
PRIMARY EXAMINER